REMARKS

Currently, claims 1, 3-13, 15-19, 21, 25 -28, 35 and 36 are pending in the application. Claims 1, 3-13, 15-19, 21, 25 -28, are withdrawn from consideration.

I. APPLICANTS' INVENTION

The present invention relates to a removable device such as a stent-graft, intended for applications where it may be desirable to remove the device at some time following implantation. The stent-graft includes a helically-wound stent component provided with a covering of graft material having anisotropic strength properties. It is removable by gripping an end of the helically-wound stent component with a retrieval device and applying tension to the stent component in the direction in which it is intended to be withdrawn from the site of implantation. The use of such a retrieval device allows the stent-graft to be removed remotely, such as via a catheter inserted into the body at a different location from the implantation site. The design of the stent-graft is such that the stent component is extended axially while the adjacent portion of the graft separates between windings of the stent component. The axial extension of the stent component, with portions of the graft still joined to the stent component, allows the device to be "unraveled" (or "unwound") and removed through a catheter of diameter adequately small to be inserted into the body cavity that contained the stent-graft. It is removed atraumatically, without incurring significant trauma to the body conduit in which it had been deployed.

II. ELECTION/RESTRICTIONS

The Examiner has withdrawn claims 1, 3-13, 15-19, 21 and 25-28 from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention

Applicants note that claim 1 was amended in their previous paper. These amendments are incorporated into claim 1 as shown in the above listing of claims; claim 1 is indicated as withdrawn along with the other claims withdrawn by the Examiner in the previous paper mailed May 13, 2009.

III. REJECTION OF CLAIMS 35 and 36 UNDER 35 USC 112, FIRST PARAGRAPH AS FAILING TO COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT.

The Examiner has concluded that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the specification was filed, had possession of the claimed invention. He states that claims 35-36 appear directed to the elected species of figure 4B and described at page 10, lines 30-36, however they depend from claim 1 which is directed to figure 4C. He adds that the specification as originally filed failed to disclose an embodiment combining the features of perforations or patterns extending through only a portion of the graft material in combination with anisotropic material.

The application at p. 5, lines 25-28 states that "The graft material that covers the stent component ...is preferably of expanded polytetrafluoroethylene (ePTFE) made as taught by US Patent 3,953,566 to Gore." The Gore patent is very well known to those in the art of ePTFE materials and medical devices made therefrom. Figure 1 of this patent is particularly relevant, showing the microstructure of PTFE that has been expanded "uniaxially" and having therefore anisotropic properties. The '566 patent includes 15 examples, 13 of which appear to describe uniaxially expanded materials while the remaining two (Examples 3 and 8) teach biaxially expanded PTFE materials. When the person of ordinary skill contemplates ePTFE, it is typically considered to be uniaxially expanded (and therefore anisotropic) ePTFE unless specifically described otherwise.

The specification provides a similar description of uniaxially-expanded, anisotropic ePTFE; see, for example, page 11, lines 3-22. The preceding paragraph at page 10, lines 30-36 (referred to by the Examiner as noted above) teaches the use of perforations through or partially through the graft material to weaken it for subsequent tearing during removal. The instant specification (also as noted above) teaches that the preferred graft material is ePTFE. Accordingly, it would be entirely apparent to the person of ordinary skill that the ePTFE material could optionally perforated as described by claims 35 and 36.

Indeed, it is well appreciated by those of skill in the art of ePTFE materials that the described methods of perforation will work perfectly well with ePTFE. See, for example, the descriptions of perforations created in ePTFE provided in US 6,352,561 to Leopold et al. that is directed to implantable medical devices. Figure 1 of this patent shows a sheet

102, optionally of ePTFE, having a series of perforations 118 formed by methods such as laser drilling (col. 6, lines 12-14 and col. 7, lines 2-5 and 29-30). There are other patents that teach perforations in ePTFE.

Clearly, if ePTFE is stated to be the preferred graft material, and the specification teaches that the graft material may be perforated (by various means all of which are fully applicable to ePTFE), any person skilled in the art has been fully enabled to make the invention described by claims 35 and 36, and as such, the requirement of the first paragraph of 35 USC 112 has been fulfilled.

CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance. If there remain any issues that might benefit from further discussion, the Examiner is requested to telephone the undersigned practitioner; likewise, the Applicants request an interview if such issues may remain.

Respectfully Submitted,

Wayne D. House

Wayne D. House 34,623
W. L. Gore & Associates, Inc.
551 Paper Mill Road
P.O. Box 9206
Newark, DE 19714-9206
(928) 864-2574

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